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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/834,438      | 04/13/2001  | Paul G. Alchas       | P-4498P2            | 2953             |

7590 10/03/2003

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EXAMINER

THANH, LOAN H

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/834,438

Applicant(s)

ALCHAS ET AL. *ad*

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17, 24-35, 41, 42, 48-58, 61-65 and 71-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 17, 18, 26-30, 41, 42, 50-55, 61, 64, 65 and 73 is/are rejected.
- 7) ☒ Claim(s) 5-10, 31-35, 56-58, 62 and 63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/15/03 has been entered.

### ***Election/Restrictions***

Applicant is reminded of the election of the species direct to figures 1-3 wherein the skin-engaging surface is flat and continuous in paper no. 8.

An action on the merits now follows.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plane within about 15 degrees or 5 degrees must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 17-18, 26-29, 41-42, 50, 51, 53-55, 61, 64, 65, 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinicke ( U.S. Patent No. 4,834,704).

Reinicke discloses a an intradermal needle assembly comprising a hub portion , a needle cannula ( 4) a limiter portion (2) having a generally flat skin engaging surface ( 2b) extending in a plane generally perpendicular to the axis of the needle. The needle cannula and limiter portion is non-movable with respect to each other. See figure 5. Reinicke discloses the forward tip to extend beyond the skin engaging surface (2b) a distance approximately 0.5 mm to 3.0 mm See col. 4, line 3. the functional limitations are met since the device of Reinicke can perform the function. The plane generally perpendicular to the needle axis is within about 15 or 5 degrees. The abutment is considered to be shown in figure 5. the Examiner has given the broadest interpretation of the claim language. The hub portion is considered the 2c.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-25,48-49,71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinicke in view of Reich (U.S. Patent No.5,672,883).

See above Reinicke discloses the invention as substantially claimed. However, Reinicke is silent to a forward and rearward cap that encloses the needle assembly there between. Reich teaches a container for storing needle assemblies with a forward and rearward cap for safe handling and transporting of needle assemblies. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the assembly of Reinicke with a rearward and forward cap as taught by Reich for safe handling of needle assemblies under government regulations.

Claims 4,30, 52 are rejected under 35 U.S.C. 103 as being unpatentable over Reinicke ( U.S. Patent No. 4834704) .

Reinicke discloses the invention substantially as claimed. See above. However, Reinicke does not disclose the hub portion and the limiter portion formed as separate pieces. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the hub and the limiter portion as separate pieces in as a

mere design choice in manufacturing. The mere fact that a given structure is integral does not preclude its consisting of various elements. In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-9, 17-18, 24-34, 41-42, 48-50, 51-57, 61-65, 71-73 have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

Claims 5-10, 31-35, 56-58, 62-63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

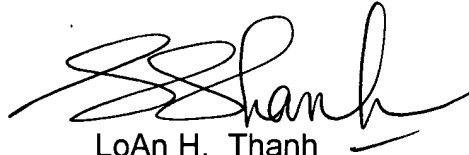
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', with a stylized flourish at the end.

LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT